Atty Doc. No. HME/7982.001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION EXAMINING OPERATIONS

In re the Application of Sharon F. Kleyne	: :	Group Art Unit: 1617
Serial No. 09/614,790	:	Examiner: Michael Willis
Filed: July 12, 2000	:	Tel. No. (703) 305-1679
For a Patent for METHOD AND KIT FOR MOISTURIZING THE SURFACE OF THE EYE	:	Date: January 13, 2003

APPELLANT'S REPLY BRIEF UNDER 37 C.F.R. §1.193(b)

Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir,

This Reply Brief is in response to the Examiner's Answer mailed on November 12, 2002. This brief is transmitted in triplicate. The following numbers relate to the numbering of the sections in the Examiner's Answer and in Appellant's Brief filed on September 24, 2002.

1 to 6. No response to the Examiner's Answer is necessary.

7. Grouping of Claims

In Section VII of Appellant's Brief, Appellant indicated that claims 75-77 stand together, claim 78 stands alone, claims 79-81 stand together, and claim 82 stands alone. Appellant understands the Examiner's Answer to indicate that the Examiner agrees that claims

75-77 stand independent from claims 79-81, but that Appellant has provided insufficient reasons why claim 78 stands alone from claims 75-77 and why claim 82 stands alone from claims 79-81.

Each of claims 78 and 82 call for an average droplet size of less than 20 microns in diameter. This is a separate patentable distinction because the prior art discloses only droplet sizes as small as 20 microns and is therefore a separate basis of patentability for these claims. This distinction is discussed on page 21 of Appellant's Brief. Appellant submits that the presence of this separate basis of patentability, as discussed in Appellant's Brief, provides sufficient reason why claims 78 and 82 stand or fall by themselves.

8-10. No response to the Examiner's Answer is necessary.

11. Reply to Examiner's Response to Appellant's Arguments

(A) Neither Embleton nor Laibovitz disclose methods for moisturizing the surface of the eye. Rather, each of these references disclose an apparatus that is used to deliver small amounts of a therapeutic compound to the eye. As disclosed in Embleton, on page 13, line 6, such therapeutic compound may include "Artificial tear/dry eye therapies, comfort drops, irrigation fluids, etc., e.g. physiological saline, water, or oil . . ."

Appellant has argued that neither Embleton nor Laibovitz discloses that dry eye can be successfully treated by application of essentially water. Dr. Rachael Garrett has submitted a Declaration on behalf of Appellant in which she declares that "Artificial tears, dry eye therapies, and comfort drops contain ingredients other than water that are essential for their beneficial effects" and that one skilled in the art would understand the disclosure of Embleton to mean

"artificial tear/dry eye therapies and comfort drops that are based upon saline, water or oil, and which include other ingredients that are necessarily present in these formulations."

The Examiner has responded to this by providing two U.S. patent references, Ogura (5,307,095) and Scheiner (5,627,611) which purportedly disclose that water is known in the art as an agent for dry eye therapy. Neither of these references, however, disclose the application of water to the surface of the eye. Rather, each of these references discloses an apparatus for maintaining a high-humidity environment surrounding the eye. Appellant submits that such a result could be achieved by a person who sits for an extensive period of time in a steam room. Ogura and Scheiner have disclosed apparatuses that provide the same high humidity as found in a steam room but which high humidity level is limited to the eye, rather than to the entire body. Thus, the prior art does not disclose the *application* of a fluid consisting essentially of water for moisturizing the surface of the eye.

The Examiner has cited MPEP 2111.03 as support for his contention that "consisting essentially of" in the present claims is correctly construed as equivalent to "comprising". Appellant submits that the Examiner's contention is incorrect.

The specification discloses that, in accordance with the invention, an amount of an aqueous fluid is applied to the surface of the eye, which amount is sufficient to rehydrate the aqueous layer of the tear film but which amount does not wash away the tear film. The specification further discloses that present day methods of moisturizing the eye, such as application of eye drops, wash away the tear film and replace it with an aqueous solutions that lack the structure of the intact tear film and replaces it with a fluid that differs from the normal aqueous layer of the tear film.

As taught in the specification, dry eye therapeutic agents other than water, which agents contain constituents that differ from constituents normally present in the tear film, are undesirable for the purpose of moisturizing the surface of the eye. It is clear from the specification and knowledge of those skilled in the art what such agents are. In the Declaration 1 of Dr. Rachael Garrett, she states that such agents include tonicity agents, viscosity increasing agents, wetting agents, preservatives, and antioxidants. Even though such agents may be irritating to the eye, they are necessary when moisturizing the eye by prior art methods which replace the tear film, or the aqueous layer of the tear film, with a moisturizing agent. But, as taught in the specification, the method of the invention permits moisturizing the eye essentially without the use of such agents.

Appellant submits that the specification discloses how such additional components would materially change the characteristics of Appellant's invention, as required by MPEP 2111.03.[1]

Thus, Appellant submits that the claims, which call for a method for moisturizing the surface of the eye and which method includes administering an aqueous formulation consisting essentially of water, patentably distinguish over the prior art.

(B) With respect to claims 79-82, the Examiner continues to insist that a "mist", as called for in claims 79-82 is consistent with a "jet or stream" as disclosed by the prior art

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[1] The specification further discloses a method for application to the surface of the of an aqueous fluid containing a therapeutic medication. This method, which is not covered by the present claims, is not intended to rehydrate the existing aqueous layer of the tear film. Therefore, this method includes the application of an aqueous fluid that does not consist essentially of water, which fluid contains a therapeutic medication and may, of course, contain other desirable agents such as tonicity, viscosity, wetting, preservative, antioxidant agents or other constituents.

Embleton reference. To bolster his assertion, the Examiner cites Appellant's proffered definition of "mist" which includes the following:

> a cloud of particles resembling this: *She sprayed a mist of perfume onto her handkerchief*. . . (emphasis in the original).

Appellant submits that one may be able to direct a mist of perfume onto a handkerchief. However, one is not able to direct a mist onto a specified target of the eye, as disclosed by Embleton in reference to a jet or stream. Embleton discloses, on page 3, lines 6-10, that:

> The jet or stream can be directed or targeted at a chosen site in an eye; eg, cornea, anterior bulbar conjunctiva, posterior bulbar conjunctiva or palpebral conjunctiva where the active compound can be readily absorbed.

Appellant further submits that, contrary to the Examiner's assertion on page 6 of his Answer, Embleton's use of "jet or stream" of droplets is not at all consistent with a mist, such as that sprayed from a perfume bottle. Such a mist does not have the specificity of directionality as does the jet or stream of Embleton.

Thus, Appellant submits that Embleton does not disclose a mist, and moreover that Embleton teaches away from a mist, as stated in Appellant's Brief.

Additionally, Appellant submits that Laibovitz does not disclose a mist and, even if Laibovitz can be construed as disclosing a mist, it is improper to combine this disclosure with that of Embleton because of Embleton's teaching away from a mist.

Laibovitz discloses drops of the size as those found in a mist. This disclosure of Laibovitz is in a section (column 3, lines 21-28) in which Laibovitz discloses the size of the droplets, not the form in which such droplets are delivered. It is possible to deliver droplets in a

mist or in a jet or stream of droplets. By necessity, in order to be a mist, the droplets must be of a certain small size. A jet or stream likewise may be of droplets of such small size. Appellant submits that Laibovitz's disclosure of such droplet sizes does not indicate that the drops are delivered as a mist, but rather that such droplets are of mist-droplet size. Because the droplets of Laibovitz are delivered to a desired site, see column 3, lines 17-19, the device of Laibovitz is understood to produce a jet or stream of droplets, which droplets are of very small size, that is of a size that would be found in a mist..

Accordingly, Appellant submits that the claims calling for a mist distinguish over the cited prior art, not only because the prior art does not disclose the use of a mist for moisturizing the surface of the eye but also because the combination of the Embleton reference (teaches away from a mist) with the Laibovitz reference (droplets the size found in a mist) is improper.

CONCLUSION

For these reasons, Appellant respectfully submits that the Examiner has improperly rejected the claims over the disclosure of the prior art and requests that the claims be found to be patentable.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on January 13, 2003.

Dated: 1/13/03

Howard M. Eisenberg

FEE TRANSMITTAL for FY 2003

Patent fees are subject to annual revision.

Complete If Known	
Application Number	09/614,790
Filing Date	July 12, 2000
First Named Inventor	Sharon F. Kleyne
Examiner Name	Michael Willis
Art Unit	1617
Attorney Docket No.	HME/7982.001

☒ Applicant claims small entity status. See 37CFR 1.27

TOTAL AMOUNT OF PAYMENT $0

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None

☐ Deposit Account

Deposit Account Number: 50-1773

Deposit Account Name: Howard Eisenberg

The Commissioner is authorized to:(check all that apply)

☒ Charge fees indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) during the pendency of this application

☒ Charge any fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Code	Large Entity ($)	Small Entity Code	Small Entity ($)	Fee Description	Fee Paid
1001	740	2001	370	Utility filing fee	
1002	330	2002	165	Design filing fee	
1003	510	2003	255	Plant filing fee	
1004	740	2004	370	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	
				SUBTOTAL (1)	$0

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

		Extra Claims	Fee from below	Fee Paid
Total Claims	-20** =	0	x 18 =	0
Indep. Claims	- 3** =	0	x 84 =	0
Multiple Dependent			=	0

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	84	2201	42	Independent claims in excess of 3
1203	280	2203	140	Multiple dependent claim, if not paid
1204	84	2204	42	**Reissue independent claims over original patent
1205	18	2205	9	*Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) $0

*or number of previously paid, if greater. For reissues, see below.

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge-late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for ex-parte reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1840*	1805	1840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	400	2252	200	Extension for reply within second month	
1253	920	2253	460	Extension for reply within third month	
1254	1,440	2254	720	Extension for reply within fourth month	
1255	1,960	2255	980	Extension for reply within fifth month	
1401	320	2401	160	Notice of Appeal	
1402	320	2402	160	Filing a brief in support of an appeal	
1403	280	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,280	2453	640	Petition to revive - unintentional	
1501	1,280	2501	640	Utility issue fee (or reissue)	
1502	460	2502	230	Design issue fee	
1503	620	2503	310	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt.	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	740	2809	370	Filing a submission after final rejection (37 C.F.R. 1.129(a))	
1810	740	2810	370	For each additional invention to be examined (37 CFR 1.129(b))	
1801	740	2801	370	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	
				Other fee (specify)	

* Reduced by Basic Filing Fee Paid **SUBTOTAL (3)** $0

SUBMITTED BY

Complete (if applicable)

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Signature				Date	January 13, 2003

AF/3p 1600

OIPE JC64 JAN 21 2003 PATENT & TRADEMARK OFFICE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/614,790
Filing Date	July 12, 2000
First Named Inventor	Kleyne, Sharon
Group Art Unit	1617
Examiner Name	Michael Willis
Total Number of Pages in this Submission: 23	Attorney Docket Number: HME/7982.001

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☒ Fee Transmittal Form	☐ Assignment Papers (for an application)	☐ After Allowance Communication to Group
☐ Fee Attached	☐ Drawings	☒ Appeal Communication to Board of Appeals and Interferences (Reply Brief - in triplicate)
☐ Amendment/Response	☐ Licensing-related Papers	☐ Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
☐ After Final	☐ Petition Routing Slip (PTO/SB/69) and Accompanying Petition	☐ Proprietary Information
☐ Affidavit(s)/Declaration(s)	☐ Petition To Convert to a Provisional Application	☐ Status Letter
☐ Extension of Time Request	☐ Power of Attorney, Revocation, Change of Correspondence Address	☐ Additional Enclosure(s) (please identify below)
☐ Express Abandonment Request	☐ Terminal Disclaimer	
☐ Information Disclosure Statement	☐ Small Entity Statement	
☐ Certified Copy of Priority Document(s)	☐ Request for Refund	
☐ Response to Missing Part(s)/ Incomplete Application		
☐ Response to Missing Parts under 37CFR 1.52 or 1.53		

Remarks:

FEE VALUE ACCOUNTABILITY
DEPOSIT ACCOUNT NO. 50 1773
FEE CODE | VALUE FURNISHED

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

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Signature	
Date	January 13, 2003

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on this date.

Type or print name	Howard Eisenberg		
Signature		Date	January 13, 2003